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K080508
PG. 1 OF 3

SECTION 2.0 – SUMMARY OF SAFETY AND EFFECTIVENESS

March 05, 2008

This summary is being included in the Premarket Notification submission in lieu of a statement of availability.

COMPANY NAME, ADDRESS AND TELEPHONE NUMBER

Lake Region Manufacturing, Inc. d/b/a Lake Region Medical (LRM)
340 Lake Hazeltine Drive
Chaska, MN 55318

PRIMARY CONTACT PERSON		ALTERNATE CONTACT PERSON
Telephone:	(952) 448-5111, Ext. 6381	(952) 448-5111, Ext. 6727
Fax:	(952) 448-3441	(952) 448-3441
Email:	dpal@lakergn.com	kmortensen@lakergn.com
Contact Person:	Deep Pal	Karen Mortensen
Title:	Regulatory Affairs Specialist	Manager, Regulatory Affairs

ESTABLISHMENT REGISTRATION NUMBER

2126666

DEVICE TRADE NAME/PROPRIETARY NAME

Mandrel Guidewire **Or** M-Wires™

DEVICE COMMON NAMES/USUAL NAMES/CLASSIFICATION NAMES

These devices are commonly known as Guides, Guidewires, or spring Guidewires. The current classification names and product codes are Urological Catheter and Accessories, Biliary Catheter and Accessories and Endoscope and Accessories.

CLASSIFICATION OF DEVICES

This type of Guidewire was originally listed as a Class II device by the Gastroenterology/Urology Review Panel; Urological Catheter and Accessories (21 CFR 876.5130) - KOD, Urological Catheter and Accessories (21 CFR 876.5130, *which is now Exempt*) – KNY, Biliary Catheter and Accessories (21 CFR 876.5010) - FGE and Endoscope and Accessories (21 CFR 876.1500) - KOG respectively.

APPLICABILITY OF PERFORMANCE STANDARDS

LRM has determined that no mandatory performance standards have been established for these devices under Section 514 of the Medical Amendments to Federal Food, Drug, and Cosmetic Act or by any subsequent regulatory action. LRM has also determined that there are no applicable voluntary standards.

DEVICE DESCRIPTION

Nitinol or Stainless Steel core wire with Palladium coil secured to the ground, flexible (distal) end of the core. The core wire can be either uncoated or coated with PTFE (Polytetrafluoroethylene). Portions of the Guidewire can also be subsequently coated with silicone MDX4-4159 Fluid. The Guidewires are bound by the following parameters:

OUTSIDE DIAMETER:	.014" - .035"
LENGTHS:	60 cm - 500 cm
TIPS:	Straight or shaped with various tip flexibilities.
COIL LENGTH:	2cm - 30 cm

SECTION 2.0 – SUMMARY OF SAFETY AND EFFECTIVENESS (continued...)

TECHNOLOGICAL CHARACTERSTICS

The design specifications are substantially similar to the existing Mandrel Guidewires. Material used for the coil of the Guidewire will be Palladium.

QUALITY SYSTEM CONTROLS

DESIGN CONTROL

LRM is in conformance with the design control procedure requirements as specified in 21 CFR 820.30. Risk analysis was completed by means of a Failure Mode and Effect Analysis (FMEA) and all verification and validation activities resulted in the ability to demonstrate that the predetermined acceptance criteria were met.

MATERIAL/SUPPLIER/PRODUCT/PROCESS CONTROLS

LRM has formal quality systems in place to assure that each product manufactured remains equivalent to the predicate products, and that the changes will not have an adverse affect on the safe and effective use of the product. The quality systems include Engineering Change Order Review, Material Qualification, Supplier Qualification, Product Qualification, and Process Qualification. These controls are applied to each product size/group.

QUALIFICATION TESTING

NON-CLINICAL TESTS

In order to demonstrate equivalence of the Mandrel Guidewire iterations, LRM performed testing to established requirements. Test pieces were tested and inspected according to established specific inspection criteria requirements for visual/tactile, dimensional and mechanical attributes. The results of these tests demonstrated the functionality and performance characteristics of these Guidewires are comparable to the currently marketed devices.

BIOCOMPATIBILITY TESTING

Biocompatibility testing per ISO 10993 series has been performed on the Mandrel device and has been found to be acceptable.

SUBSTANTIAL EQUIVALENCE DATA

Lake Region believes the Mandrel Guidewire iterations are substantially equivalent to the predicate devices cleared under 510(k) *K970994*. All non-clinical test results support the claim of substantial equivalence to the predicate devices.

INTENDED USE STATEMENT

To facilitate the introduction of other diagnostic and treatment devices used in gastroenterology and urology procedures.

NOTE: The modification of this device does not alter its intended use.

SECTION 3.0 – PROPOSED LABELING

3.1 LABELS, LABELING AND ADVERTISING

LRM produces cardiovascular and vascular Guidewires on an OEM basis for other manufacturers, kit assemblers, and distributors. There is no direct distribution by Lake Region.

An example of a typical single pack label is included in this section.

3.2 INTENDED USE STATEMENT

To facilitate the introduction of other diagnostic and treatment devices used in gastroenterology and urology procedures.

NOTE: The modification of this device does not alter its intended use.

3.3 INSTRUCTIONS FOR USE

A draft example of a typical "Instructions for Use" for the Mandrel Guidewires is included in this section.

3.4 ADVERTISING/PROMOTIONAL MATERIALS

LRM has no advertising or promotional materials intended for distribution to the end-users of this product.

➢ **The following pages contain labeling information including:**

- *Sample label for proposed device*
- *Sample IFU for proposed device*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAR 21 2008

Mr. Deep Pal
Regulatory Affairs Specialist
Lake Region Medical
340 Lake Hazeltine Drive
CHASKA MN 55318-1029

Re: K080508
Trade/Device Name: Mandrel Guidewire or M-Wire™
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCY
Dated: February 22, 2008
Received: February 25, 2008

Dear Mr. Pal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K080508

Device Name: Mandrel Guidewires

Indications for Use:
To facilitate the introduction of other diagnostic and treatment devices used in gastroenterology and urology procedures.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K080508